



K 962664

510(k) Summary (21 CFR 807.92)

SEP 10 1996

ELECTRA 1800C Automatic Coagulation Analyzer

- **Submitter:** Medical Laboratory Automation, Inc.
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- **Device:** ELECTRA 1800C Automatic Coagulation Analyzer
Common Name: Automated Coagulation Instrument
Classification Name: Coagulation Instrument (as per 21 CFR 864.5400)
- **Predicate Device:** ELECTRA 1600C™ Automatic Coagulation Timer (K931206)
- **Device Description:**

A detailed description of the device, including an explanation of how it functions and the basic scientific concepts, are described in the ELECTRA 1800C Operator's Manual, Chapter 1 - Getting Started..

- **Intended Use:**

The ELECTRA 1800C is an in vitro diagnostic instrument which may be categorized as an automatic coagulation timer and photometric analyzer, for the performance of both coagulation and chromogenic testing. Coagulation testing capabilities of the proposed product include routine clotting tests such as prothrombin time (PT), activated partial thromboplastin time (APTT), factor assays, fibrinogen, and thrombin time. Chromogenic testing capabilities include tests such as Antithrombin III.

- **Device Comparison:**

The proposed product, ELECTRA 1800C, is essentially equivalent in design to the ELECTRA 1600C™ Automatic Coagulation Analyzer. Basic system technology remains unchanged. The sample mechanism has been modified to allow for closed tube sampling. This modification has been included to limit operator exposure to bloodborne pathogens by eliminating standard practices such as removing tube stoppers for instrument sampling.